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NCIC HPV
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Subject: Environmental Defense comments on Hexanedinitrile Hydrogenated, High Boiling Fraction (Crude BHMT) CAS# 68411-90-5

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Subject: Environmental Defense comments on Hexanedinitrile Hydrogenated, High Boiling Fraction (Crude BHMT) CAS# 68411-90-5

(Submitted via Internet 6/25/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, Edwin.L.Mongan-1@usa.dupont.com, and Rauckman@toxicsolutions.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Hexanedinitrile Hydrogenated, High Boiling Fraction (Crude BHMT) CAS# 68411-90-5.

E.I. duPont de Nemours & Co. and Solutia, Inc., in response to EPA's High Production Volume Challenge, have submitted a proposed Test Plan and Robust Summary for hexanedinitrile hydrogenated, high boiling fraction, also known as crude BHMT. This submission has a somewhat unique format in that what appears to be the Test Plan is labeled "Robust Summary" and what appear to be Robust Summaries of research studies for crude BHMT and refined BHMT are labeled Appendix A and Appendix B, respectively. Appendices A and B contain more detail than necessary, particularly on methods, statistical methods used, etc., but do summarize a number of studies, some of which are recent and were conducted under GLP.

The "Robust Summary" explains that crude BHMT is essentially a residue that remains after the distillation of hexamethyl diamine and is thus of variable composition, consisting primarily of bis-hexylmethylenetriamine, 50 to 70%. Other constituents of the mixture are oligomeric amines, hexamethylenediamine, caprolactam, adiponitrile and small amounts of related compounds. A brief review of the literature indicates that, with the exception of caprolactam, which was a negative carcinogen in chronic studies, most of the chemicals found in crude BHMT have been subjected to only very limited toxicological testing. However, studies described for crude BHMT indicating that it is moderately toxic and is not mutagenic suggest that individual constituents of the mixture are likely not highly toxic or mutagenic.

Our review of Table 1 of the "Robust Summary", Matrix of Available and Adequate Data on Crude BHMT and BHMT, indicates that duPont and Solutia feel that most of the SIDS elements have been addressed by adequate studies of crude BHMT or bridged from studies of refined BHMT. SIDS elements not adequately addressed are those for short-term studies of aquatic toxicity to daphnia and algae, and these studies are proposed.

Data addressing mammalian toxicity are presented; however, our review of data described in subsequent tables raises some comments and questions. First, we note that tables presenting toxicological data do not describe the species used in the various studies. This information can currently be

obtained only by review of the Appendixes, and should also be included in the tables in the "Robust Summary". Second, we note that the toxicity data seem inconsistent. For example, data presented in Table 5 indicate an oral LD50 of 450 mg/kg and that a dermal dose between 126 and 200 mg/kg killed 100% of the treated animals. Appendix A indicates the oral data were obtained in a study using rats and the dermal data were obtained in a study using rabbits. While the species difference may account for the difference in results, this issue should be discussed and explained. Another variance is seen in a study described on page 60 of Appendix A that indicates no signs of toxicity in rats receiving a dose of 200 mg/kg and minimal toxicity at 670 mg/kg. These results appear to conflict with those from the first study, a point that warrants explanation or comment and possible further study. Third, the statement is made that the mammalian toxicity of crude BHMT and refined BHMT are similar. Since the only data provided for comparison are those for the acute lethal dose of each compound (in Table 5), this broad statement is not supported by available data. In fact, no other data are presented for mammalian toxicity of refined BHMT, and data for an acute lethal dose is not adequate to characterize the acute toxicity of BHMT, as indicated in Table 1. And finally, given that everything is nontoxic at some dose, Tables 4, 5, 6 and 7 of the "Robust Summary" should include descriptions of the dose ranges administered in each study.

The sponsor states that, since bis-hexylmethylenetriamine accounts for 50% or more of crude BHMT, the fate of this mixture in the environment should be similar to that of refined BHMT. We do not agree with this statement, as the fate of other constituents of this mixture may vary significantly and thus impact the risks to human and environmental health posed by the mixture. This is of particular concern because review of the uses of crude BHMT, particularly its use in asphalt which results in direct release into the environment, indicates significant potential for human and environmental exposure.

In summary, we appreciate the fact that crude BHMT is a complex and varying mixture and as such it is difficult to study. Nevertheless, this mixture of chemicals is released into the environment in large quantities and should therefore be subject to closer scrutiny than has been the case to date. Specifically, we feel those SIDS elements addressing environmental fate, transport and fugacity of the major constituents in addition to BHMT, and acute toxicity to fish of crude BHMT, should be addressed by additional work.

Thank you for this opportunity to comment.

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